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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,809	04/26/2002	Ronit Eisenberg	24025-501	1519

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EXAMINER

NOLAN, PATRICK J

ART UNIT PAPER NUMBER

1644

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/009,809

Applicant(s)

EISENBERG ET AL.

Examiner

Patrick J. Nolan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 44,46,52-57,59,60 and 63-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 44,46,52-57,59,60,63 and 65-74 is/are rejected.
- 7) ☒ Claim(s) 64 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8-24-05</u> . | 6) <input type="checkbox"/> Other: _____  |

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1. Claims 44, 46, 52-57, 59-60 and newly added claims 63-74 are pending.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 44, 46, 52-57, 59-60 and newly added claims 63 and 66-74 are rejected under 35 U.S.C. § 103 as being unpatentable over Kubby et al., (U), in view of Aridor et al. (V), and U.S. Patent 5,807,746 (A), both of record for reasons set forth the Office Action mailed 4-8-05.

Applicant's arguments of 8-24-05 have been fully considered but are not found persuasive.

The declaration under 37 CFR 1.132 filed 8-24-05 is insufficient to overcome the rejection of claims 44, 46, 52-57, 59-60 based upon 35 USC 103 as set forth in the last Office action.

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Applicant's arguments and the declaration present essentially the same arguments, so they will be addressed together.

Applicant argues that there was no expectation of success that using any importation molecule with an anti-allergic peptide would result in treating an allergic condition in vivo and in vitro. The evidence they present is twofold, their own specification teaches that use of two different importation molecules VTLVLALGALAGVGVG and RQPKIWFPNRRKPWKK led to no anti-allergic effect either in vitro or in vivo. Secondly they argue that in the Lin patent the importation peptide complexed with the importation peptide was not as effective in stimulating mitosis as the mitogenic peptide given without the importation peptide. They argue there was no expectation that the importation peptide taught by Lin et al., linked to anti-allergic peptide taught by Aridor would have treated allergy in vivo.

However, the importation peptide in the Lin patent did import the mitogenic peptide into the cell and did exert a mitogenic effect. It may not have done it as well as the mitogenic peptide alone, but it did work. So the expectation that the Lin importation peptide would work, based on the evidence Applicant has argued is there. Secondly, Applicant's arguments that because two of their three importation peptides did not work, that the third was unexpected is not found persuasive because the third was recognized to work in vitro by the Lin patent and was expected to work in vivo as taught by the Lin patent. Applicant has provided insufficient evidence as to why one of skill in the art at the time the invention was made would have not reasonably expected the Lin importation peptide to work in vivo, given its in vitro efficacy.

The new ground of rejection is necessitated by Applicant's amendment filed 8-24-95

3. Claims 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuby et al., in view of Aridor et al., and US Patent 5,807,746 as applied to claim 63 above, and further in view of US Patent 6,103,692, all of references are of record.

The Kuby et al., Aridor et al., and '746 patent have been discussed supra. The claimed invention differs from the prior art teachings from the recitation of adding succinylation to the peptide.

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However, the '692 patent teaches that succinylation of peptides increases the ability of the peptide to pass through the cell membrane and into the cell.

Therefore one of skill in the art would have been motivated to succinylate the peptide made obvious by Kuby et al., Aridor et al., and the '746 patent, because succinylation increases transport through the cell membrane, a necessary feature for mast cell degranulation inhibitory peptide as taught by Aridor et al. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

4. It is noted that claim 64 is objected as being dependent upon a rejected claim.

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

5. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

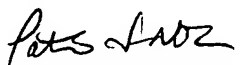
6. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

  
Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

October 21, 2005